



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

CMS-3262-FN

Medicare and Medicaid Programs; Approval of the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) for Continuing CMS Approval of its Ambulatory Surgical Center Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) for continued recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that wish to participate in the Medicare or Medicaid programs.

EFFECTIVE DATE: This final notice is effective November 27, 2012 through November 27, 2018.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC) provided certain requirements are met. Section 1832 (a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as an ASC. Regulations concerning provider agreements are at 42 CFR part 489 and

those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 416 specify the conditions that an ASC must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for ASCs.

Generally, to enter into an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in 42 CFR part 416. Thereafter, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at §488.4 and §488.8(d)(3). The regulations at

§488.8(d)(3) require an accrediting organization to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

American Association for Accreditation of Ambulatory Surgery Facilities (AAAASFs) current term of approval for their ASC accreditation program expires November 27, 2012.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides us with 210 days from receipt of a complete application, with any documentation necessary, to make the determination and to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30 day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On June 22, 2012, we published a proposed notice in the **Federal Register** (77 FR 37678) announcing AAAASF's request for continued approval of its ASC accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at §488.4 and §488.8, we conducted a review of AAAASF's application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of AAAASF's-- (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training,

monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.

- The comparison of AAAASF's accreditation to CMS's current Medicare ASC conditions for coverage.
- A documentation review of AAAASF's survey process to--
 - + Determine the composition of the survey team, surveyor qualifications, and AAAASF's ability to provide continuing surveyor training.
 - + Compare AAAASF's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
 - + Evaluate AAAASF's procedures for monitoring ASCs found to be out of compliance with AAAASF's program requirements. The monitoring procedures are used only when AAAASF identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at §488.7(d).
 - + Assess AAAASF's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.
 - + Establish AAAASF's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.
 - + Determine the adequacy of staff and other resources.
 - + Confirm AAAASF's ability to provide adequate funding for performing required surveys.
 - + Confirm AAAASF's policies with respect to whether surveys are announced or

unannounced.

+ Obtain AAAASF's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the June 22, 2012 proposed notice also solicited public comments regarding whether AAAASF's requirements met or exceeded the Medicare conditions for coverage for ASCs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between AAAASF's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared AAAASF's ASC requirements and survey process with the Medicare conditions for coverage and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of AAAASF's ASC application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at §416.41(b)(2), AAAASF revised its standards to ensure the ASC's transfer agreement is with a local, Medicare-participating hospital that meets the requirements for emergency services.
- To meet the requirements at §416.44(a)(2), AAAASF revised its standards to address the requirement that "the ASC must have a separate recovery room and waiting area."
- AAAASF revised its crosswalk to ensure that all regulatory references are correct for the following citations: §416.42(a)(2), §416.42(c)(2), §416.44(c)(3), §416.50(c)(1), §416.50(e), and §416.50(g).

- To meet the requirements at §488.4(a)(4), AAAASF modified its policies to ensure all personnel files are accurate and complete.
- To meet the requirements at §488.4(a)(5), AAAASF modified its policies to improve the accuracy and consistency of data submissions to CMS.
- To meet the requirements at §488.4(a)(6), AAAASF modified its policies to ensure all compliant investigations are conducted in accordance with the requirements in chapter Five of the SOM.
- To meet the requirements at §488.6(a), AAAASF revised its policies and procedures to ensure deemed status survey files are complete and accurate.
- To meet the requirements at §488.12, AAAASF modified its policies to ensure all pertinent survey information, including all surveys conducted, is included in the final accreditation decision letters.
- To meet the medical record requirements at Appendix L of the SOM, AAAASF revised its policies to ensure surveyors review the required number of medical records during a survey.
- To meet the requirements at Section 2728 of the SOM, AAAASF modified its policies regarding timeframes for sending and receiving a plan of correction.
- To meet the requirements at Section 3012 of the SOM, AAAASF modified its policies to ensure follow-up, focused surveys for condition level noncompliance are conducted timely.
- To meet the requirements at Section 2700A of the SOM, AAAASF modified its policies to ensure all surveys are conducted unannounced.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that AAAASF's requirements for ASCs meet or exceed our requirements. Therefore, we approve AAAASF as a national accreditation organization for ASCs that request participation in the Medicare program, effective November 27, 2012 through November 27, 2018.

V. Collection of Information Requirements

This document does not impose any information reporting, recordkeeping or third-party disclosure requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

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Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare--ASC Insurance Program; and No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: November 20, 2012

Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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